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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,830	10/09/2000	Alexander Gaiger	210121.465C3	4595

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EXAMINER

SCHWADRON, RONALD B

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/04/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/685,830

Applicant(s)

Gaiger et al.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18, 24, and 47-55 is/are pending in the application.
- 4a) Of the above, claim(s) 48, 49, 51, 52, 54, and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-18, 24, 47, 50, and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

1. Applicant's election of Group VII and the species SEQ. ID. 2 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been MPEP § 818.03(a))
2. Claims 1-15,19-23,25-46,48,49,51,52,54,55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.
3. Claims 16-18,24,47,50,53 are under consideration. Claims 1-15,19-23,25-46 have been canceled.
4. The abstract of the disclosure is objected to because it does not disclose the claimed invention (eg. the method of claim 18). Correction is required. See MPEP § 608.01(b).
5. As per the declaration filed with the instant application, if applicant intends to claim priority to application 09/684361 then applicant needs to amend the first sentence of page 1 of the specification to include a priority claim to said application.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 47,50,53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "polypeptide consists of no more than amino acids 1-249 of WT1 and wherein said polypeptide comprises the amino acid sequence set forth in SEQ. ID. NO:2" in claims

47,50,53. Applicant has indicated that said phrase finds support in the specification, page 52, line 23. However, said disclosure is limited to a particular construct containing amino acids 1-249 of WT1. It does not disclose smaller peptides that contain SEQ. ID. NO:2 as per the instant limitation. The scope of the written description provided in the specification is not commensurate with the scope of the claimed invention (eg. the claimed invention constitutes new matter).

8. Claims 16-18,47,50,53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", *Vas-Cath, Inc. V. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed peptides.

The instant claims recite a variant peptide wherein said peptide encodes an immunogenic WT1 peptide wherein said peptide binds human MHC (eg. T cell binding requires MHC binding of the peptide). The claims encompass a variant peptide wherein said peptide encodes an immunogenic peptide wherein said peptide binds antisera against WT1. The art recognizes that there are hundreds of different allotypes of MHC molecules found in humans, wherein each allotype binds a unique set of peptides not bound by a different allotype. The specification provides written description of particular peptides that bind WT1 antisera. The claims encompass immunogenic WT1 peptides per se, wherein the specification provides specific examples of a limited set of actual immunogenic WT1 peptides. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the

inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. In the instant case, the specification has disclosed specific immunogenic peptides which bind MHC or antiWT1 antisera, while claiming peptides which bind any human MHC or antisera against WT1. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is indefinite in that it refers to canceled claim 1.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 16-18,24,47,50,53 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Chada et al. (US Patent 5,693,522) as evidenced by Berzofsky et al.

Chada et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell responses are administered to a patient (see column 1, second paragraph, column 2, column 4, second paragraph, and last paragraph, continued on column 5, column 8, column 14, last two paragraphs and column 15). Chada et al. teach that said WT1 peptide is administered with a pharmaceutically acceptable carrier (see column 15, second paragraph). Chada et al. teach that said WT1 peptide is administered with a non-specific immune enhancer (see column 15, third paragraph). Chada et al. teach use of peptides which induce T cell mediated responses (see column 14, last paragraph, continued on page 15 and column 15, first paragraph) wherein the art recognizes that such peptides can have less than 16 amino acids (eg. see Berzofsky et al., page see page 42, lines 18-21). Chada et al. teach that the aforementioned peptide can be used to treat the WT1 positive Wilms' tumor (see column 8, penultimate paragraph). The peptide taught by Chada et al. comprises SEQ. ID. no. 2 (eg. it encompasses use of use of intact WT1, see column 14, last paragraph). The variants of claims 47,50,53 are encompassed by intact WT1 taught by Chada et al. (the peptide recited in the claim with amino acids added) or any immunogenic WT1 peptide (eg. one or more substitutions).

13. Claims 16,18,24,47,50,53 are rejected under 35 U.S.C. 102(b) as being anticipated by Berzofsky et al. (WO 94/21287).

Berzofsky et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell responses are administered to a patient (page 4, first paragraph and claims 1, 5,11,16). Berzofsky et al. teach that said WT1 peptide is administered with a pharmaceutically acceptable carrier (see page 7, lines 1-2.). Berzofsky et al. teach that said WT1 peptide is administered with a non-specific immune enhancer (a dendritic cell). Berzofsky et al. teach use of peptides which induce T cell mediated responses wherein the peptide can be the minimal peptide that can bind MHC (see page 14, first incomplete paragraph) wherein said minimal size is around 10 amino acids (see page 42, lines 18-21). Berzofsky et al. teach that the aforementioned peptide can be used to treat the WT1 positive Wilms' tumor (see pages 14-16). The peptide taught by Berzofsky et al. comprises a variant of SEQ. ID. no. 2 as per recited in the claims (eg. it encompasses use of use of any WT1 peptide).

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 16,18,24,47,50,53 rejected under 35 U.S.C. 103(a) as being unpatentable over Chada et al. in view of Herlyn et al. (WO 95/29995).

Chada et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell or B cell responses are administered to a patient (see column 1, second paragraph, column 2, column 4, second paragraph, and last paragraph, continued on column 5, column 8, column 14, last two paragraphs and column 15). Chada et al. teach that said WT1 peptide is administered with a pharmaceutically acceptable carrier (see column 15, second paragraph). Chada et al. teach that said WT1 peptide is administered with a non-specific immune enhancer (see column 15, third paragraph). Chada et al. teach that the aforementioned peptide can be used to treat the WT1 positive Wilms' tumor (see column 8, penultimate paragraph). The peptide taught by Chada et al. comprises SEQ. ID. no. 2 (eg. it encompasses use of use of intact WT1, see column 14, last paragraph). Chada et al. do not teach that said peptide consists of no more than amino acids 1-249 of WT1 and comprises SEQ. ID. NO. 2. Herlyn et al. teach a peptide that consists of no more than amino acids 1-249 of WT1 and comprises SEQ. ID. NO. 2 (eg. see page 19, last paragraph wherein SEQ. ID. No:2 is found in amino acids 1-181 of human WT1), wherein said peptide is immunogenic (eg. it induces antibodies, see page 20). Herlyn et al. teaches that Mabs produced by immunizing animals with said peptide can be used to treat human disease (see page 17). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Chada et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell or B cell responses are administered to a patient whilst Herlyn et al. teach a peptide comprising SEQ. ID No:2, wherein said peptide is immunogenic (eg. it induces antibodies, see page 20). One of ordinary skill in the art would have been motivated to do the aforementioned because Chada et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell or B cell responses are administered to a patient (see column 1, second paragraph, column 2, column 4, second paragraph, and last paragraph, continued on column 5, column 8, column 14, last two paragraphs and column 15). The peptide taught by Herlyn et al. would stimulate T cells because the art recognizes that an antibody response against protein antigens requires T helper cell stimulation.

16. No claim is allowed.

17. Papers related to this application may be submitted to Group 1600 by facsimile

transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



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PRIMARY EXAMINER
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Art Unit 1644